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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,219	07/09/2001	Mark S. Schaberg	54670USA1A.002	6255

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/901,219	Applicant(s) SCHABERG ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' supplemental IDS, filed 09/23/2002; and response to the previous office action, filed 12/23/2002.

Claims 1-30 are included in the prosecution.

The standing rejections:

(1) Claim Rejections - 35 USC § 103

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '902 in view of any of US 6,193,996 ('996) or WO 96/08229 ('229) and may or may not in view of US 2002/0110585 ('585).

US '902 disclosed a composition comprising a drug in a polymer carrier (abstract). The polymer comprising pyrrolidonoethyl methacrylate polymerized with alkyl acrylate monomer and monomer comprising carboxylic acid (col.2, lines 30-32, 57-58; col.3, lines 1-2, 20-22). The number of carbon atoms is inherent for the monomer.

The reference does not teach the macromonomer, the backing for the transdermal delivery, the particular antimicrobial agents, nor the species of the alkyl acrylate.

US '996 teaches a pressure sensitive comprising a copolymer of one or more alkyl acrylates or (meth)acrylates containing 4-12 carbon atoms and one or more

hydrophilic monomers. Examples of the alkyl acrylates include butyl, isooctyl, cyclohexyl and 2-ethylhexyl acrylates (abstract; col.2, lines 53-66). Hydrophilic monomers include carboxylic acid containing monomers, vinyl acetate and amino containing monomer (col.3, lines 1-14). The copolymer further comprising macromer, such as polymethylmethacrylate and softener, such as ethylene glycol and propylene glycol (col.3, lines 30-67); col.4, line 61). The above composition is applied into a backing (col.5, lines 21-24).

WO '229 discloses a transdermal drug delivery device comprising a pressure sensitive adhesive comprising copolymer of monomers selected from alkyl acrylate containing 4-12 carbon atoms; monomers comprising functional groups selected from carboxylic acid, sulfonamide, urea, carboxamide, amine, oxy oxo, and cyano; macromonomer; drug; and softener (page 79, lines 1-25). The copolymer further comprises vinyl acetate or pyrrolidones in an amount of 0-60% (page 80, lines 1-14, 27-30). The alkyl acrylate is selected from isooctyl acrylate, ethylhexyl acrylate, butyl acrylate and cyclohexyl acrylate (page 80, lines 23-25. the macromonomer is present in an amount not more than 15% and is selected from the group containing polymethylmethacrylate (page 81, lines 15-16; page 82, lines 15-18). The softener is present in an amount of 20-60% and selected from fatty acids and fatty alcohols (page 82, lines 20-30).

It is within the skill in the art to select the drug to be delivered transdermally according to particular need. No criticality has been shown in the particular antimicrobial agents of instant claims.

US '585 teaches a transdermal drug delivery device comprising a reservoir comprising copolymer of alkyl methacrylate and monomer having functional group selected from carboxylic acid, sulfonamide, oxy oxo, amine, carbamate, carboxamide, or urea (abstract; page 4, 0039-0041). The drugs to be delivered in this reservoir include iodine compounds and chlorohexidine (page 8, 0101).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to add the additional monomers disclosed by US '996 and WO '229 to the copolymer of US 902 to provide a pressure sensitive adhesive suitable for the transdermal drug delivery, with reasonable expectation of success of the delivered adhesive in transdermal drug delivery. Motivation would arise from the teaching of WO '229 that the copolymer of the invention provide an adhesive that maintains contact with the skin and can be removed cleanly from the skin (page 3, lines 11-15), or from the teaching of US '996 that the adhesive of the copolymers allow to maintain the device in contact with the skin for a sufficient time (col.2, lines 45-48).

Applicants' Argument:

- US '902 is drawn to polymer complex carrier and nowhere the PSA is disclosed. The claimed monomers are listed within long list of monomers. PyEA is nowhere mentioned. The description of alkyl acrylate and alkyl methacrylate as a general class provides no indication that it would be beneficial of such an acrylate to contain 4-12 carbon atoms in the alkyl group.
- US '996 and WO '229 are typical transdermal drug delivery devices and no motivation to combine the materials of US '902 with other materials for the

purpose of providing pressure sensitive adhesive suitable for transdermal drug delivery device.

Examiner's Position:

- The claims are drawn to a composition, and the elements of the composition are taught by the US '902, i.e. alkyl acrylate and pyrrolidone monomer, and the preamble is not patentably significant. The reference teaches the generic concept of using alkyl acrylate and pyrrolidone monomer, and it is within the skill in the art to select species when the art discloses the genus and some species. No criticality has been shown in using PyEA over PyMEA. The alkyl group suggests any number of carbon atoms that encompass 4-12. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonable suggested to one having ordinary skill in the art, including nonpreferred embodiments. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same purpose.

- In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation would arise from the teaching of WO '229 that the copolymer of the invention provide an adhesive that maintains contact with the skin and can be removed cleanly from the skin (page 3, lines 11-15), or from the teaching of US '996 that the adhesive of the copolymers allow to maintain the device in contact with the skin for a sufficient time (col.2, lines 45-48). The rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. See *In Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

(2) The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,732,808 disclosed skin adhesive comprising alkyl acrylate, vinyl acetate, macromer and iodide.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600